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a Johnson & Johnson company

Appendix B

510 (k) Summary of Safety and Effectiveness

Submitter's name and address	Cordis Europa, NV Oosteinde 8 NL-9301 LJ Roden The Netherlands
Contact Person	Harm Hovinga Senior Regulatory Affairs Associate Tel: +31 - (5050) 22479 Fax: +31 – (5050) 22456 E-mail: hhovinga@crdnl.jnj.com
Date prepared	December 23, 2004
Device Trade Name	**InScope Precision balloon Dilator**
Common Name	**Esophageal dilator**
Classification Name	**KNQ** (21 CFR 876.5365 Esophageal dilator
Device Classification	**Class II.**
Performance standards	FDA has not (yet) established specific performance standards for this device under section 514 of the Food, Drug and Cosmetic Act.

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Product Description

The InScope Precision Balloon Dilator is a sterile, single use, disposable esophageal dilator. The InScope Precision Balloon Dilator contains three marking bands on the balloon to facilitate more precise centering the balloon within the stricture. The middle band is located at the center of the balloon at 5 cm distance from the shaft marker. The proximal and distal bands are set 2.5 cm from the centre band. The InScope Precision Balloon Dilator is provided with a stopcock to maintain pressure or vacuum. The InScope Precision Balloon Dilator is capable of 3 distinct and progressive larger diameters as a function of the applied inflation pressure. The specific pressure / diameter relationship is represented on the labeling of each product.

The subject InScope Precision Balloon Dilator described in this submission is virtually identical to its predicate device (Boston Scientific's CRE Balloon dilatation catheter), which already has received FDA 510(k) concurrence.

Intended Use

The **InScope™ Precision Balloon Dilator** is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus.

Technological comparison

Comparisons of the subject and the predicate device(s) show that technological characteristics, such as materials, mode of operation, performance properties, biocompatibility, sterilization and packaging are considered substantially equivalent to the currently marketed predicate devices,

Performance Data

The safety and effectiveness of the **InScope Precision Balloon Dilator** has been demonstrated via data collected from non-clinical bench type tests and analyses. The materials used in the subject device are found to be biocompatible.

Substantial Equivalence Statement

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A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval.
The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the FDA stated: "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. The determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2005

Mr. Harm Hovinga
Senior Regulatory Affairs Associate
Cordis Corporation, A Johnson & Johnson Company
Cordis Europa N.V.
Oosteinde 8
9301 LJ Roden, Drenthe
THE NETHERLANDS

Re: K043605
Trade/Device Name: InScope™ Precision Balloon Dilator
Regulation Number: 21 CFR §876.5365
Regulation Name: Esophageal dilator
Regulatory Class: II
Product Code: 78 KNQ
Dated: December 23, 2004
Received: December 30, 2004

Dear Mr. Hovinga:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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Appendix A: Intended Use Statement

510(k) Number (if known): K043605

Device Name: **InScope™ Precision Balloon Dilator**

Indications for Use Statement

The InScope Precision Balloon Dilator is intended for use in adult and adolescent populations to endoscopically dilate strictures of the esophagus

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043605